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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,602	06/13/2005	Guocheng Wang	16188.0002U1	8485
23859 7590 11/01/2007 NEEDLE & ROSENBERG, P.C. SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915			EXAMINER BERCH, MARK L	
			ART UNIT 1624	PAPER NUMBER
			MAIL DATE 11/01/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/534,602	Applicant(s) WANG ET AL.	
	Examiner /Mark L. Berch/	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed..
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/23/2005; 01/23/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/04774.

Note Form 1. It has a peak at about 17.2. The wording of claim 1, using and/or, means that a single peak will suffice to meet the conditions of claim 1, and those say “about 17.24”. The reference has 17.2 Claim 4 is included because the IR spectrum is usually not affected by the crystalline form to any significant degree. The reference is equivalent to US 6451340.

Claims 1-7 are rejected under 35 U.S.C. 102(a) as being anticipated by CN1396170.

It is clear that this is the same crystalline form. Gaining benefit of the 11/12/2002 application will require submitting a certified translation of the priority document.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/35460.

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The crystallization process is given in some detail on page 30. The reference is silent on the particular crystallographic form present. The references show the compound, but are silent on the particular crystallographic form. MPEP 2112 states:

“SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY

The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).”

In this case, the “unknown property” is the particular crystalline form. This is unknown because the reference is silent on this property. MPEP 2112 goes on to state:

“A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection.”

Again, the “CHARACTERISTIC” which the prior art is silent on is the crystalline form (crystalline form is considered to be in the category of chemical properties; see *Zenith Laboratories Inc. v. Bristol-Myers Squibb Co.* 30 USPQ2d 1285, 1288).

This is not an ordinary inherency situation where it is not explicitly stated what the product actually is. In every reference applied, the reference explicitly teaches exactly what the compound is. In fact, it is the opposite. In a normal inherency situation, the claim is of

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known structure, and the reference is of unknown structure. Here, the reverse is true, and hence the legal circumstances of inherency-in-the-prior-art do not apply. The only difference is the property about which the reference happens to be silent.

See for example *Ex parte Anderson*, 21 USPQ 2d 1241 at 1251, discussion of Rejection E. The claims had “numerical or functional values for certain properties which [the authors of the references] did not measure”. The PTO presented no reasoning as to why the prior art material would have been expected to have those properties. Instead, the decision states, “There is ample precedent for shifting the burden to an applicant to reproduce a prior art product whose final structure or properties are, at least, in part determined by the precise process used in its manufacture.” (page 1253).

In another example, certain claims of *Ex parte Raychem Corp.* 25 USPQ2d 1265 required a linearity ratio of less than 1.2. The decision notes that neither reference discloses any values of the linearity ratio. The PTO presented no reasoning as to what the ratio would be expected to be in the references. The Decision states: “However, this does not end the inquiry since, where the Patent and Trademark Office is not equipped to perform the needed testing, it is reasonable to shift the burden of proof to Raychem to establish that (1) the argued difference exists....”

And indeed, there have been a number of cases in which applicants have pointed to silence of the prior art with regard to this or that property: *In re Pearson*, 181 USPQ 641; *In re Zierden* 162 USPQ 102; *In re Lemin*, 140 USPQ 273; *Titanium Metals Corporation of America v. Banner*, 227 USPQ 773; *In re Benner*, 82 USPQ 49; *In re Wilder*, 166 USPQ 545; *Ex parte Kucera*, 165 USPQ 332; *General Electric Co. v. Jewel Incandescent Lamp Co.*, 67 USPQ 155; *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607; *In re Parker*, 43 USPQ

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457. Such efforts to avoid anticipation on that basis invariably failed. Going further, if silence about properties of prior art compounds could be relied on, then one could not reject over references with no utility (see *In re Schoenwald*, 22 USPQ2d 1671), since applicants could always insert the utility into the claim as a property.

It is well settled that the PTO can require an applicant to establish that a prior art product does not necessarily possess the characteristics of the claimed product when the prior art and claimed products are identical or substantially identical. An applicant's burden under these circumstances was described in *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977) as follows:

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, or 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products (footnote omitted).

Overcoming the rejection is very straightforward. One simply replicates the prior art procedure. If the claimed characteristic does not appear at all in the product, or if on repetition, it sometimes does not appear in the product, then the rejection is overcome.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-10 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims are drawn to just a single peak, or even just 4 or 5 peaks are not proper. Applicants have only invented this particular form, and thus are entitled to claim only that. Applicants are not entitled to claim any form that happens to have just these 5 peaks, because other polymorphs which also happen to have those 5 peaks have not been created by applicants, and applicants have not in fact taught how to make them. It is certainly true that two polymorphs of the same compound can have 5 peaks in common. That is, a small number of peaks is not a unique description, and applicants have not enabled making ANY form with that particular peak. All of claim 1's peaks should be required.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

AD must be defined.

Claim 9 refers to step b) and c), but there is no such steps.

Specification

The abstract states that there is a process, but does not set forth what the process actually consists of.

Page 1, line 20 should be "amorphous".

Claim Objections

Claim 9, line 2 should have "acetonitrile".

Information Disclosure Statement

Patents were struck as what was provided was just abstracts. The abstracts are cited on the PTO-892, and the Chinese patents are provided.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Mark L. Berch/ whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

. /Mark L. Berch/
Primary Examiner
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10/26/2007